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RE:	Application of:	LENEAU, Harry
	Serial No.:	10/629,880
	Filed:	July 29, 2003
	Invention:	INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT HEALTH
	Art Unit:	1615
	Examiner:	SASAN, Aradhana
	Confirmation No.:	5579
	Our Docket:	P00903-US-01 (21934.0001)

APPELLANT'S BRIEF IN SUPPORT OF APPEAL FROM FINAL REJECTION TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

The Appellant has appealed to the Board of Patent Appeals and Interferences (the "Board") from the decision of Examiner Aradhana Sasan (the "Examiner") dated September 24, 2007 (the "Final Office Action"), the first Advisory Action Before the Filing of an Appeal Brief from Supervisory Patent Examiner Michael P. Woodward (the "Supervisory Examiner") dated January 30, 2008 (the "First Advisory Action"), and the second Advisory Action Before the Filing of an Appeal Brief from the Examiner dated March 31, 2008 (the "Second Advisory

Action"), finally rejecting claims 1, 3-10, and 13 of U.S. Patent Application Serial No. 10/629,880 (the "Application"). The Appellant filed a Notice of Appeal (the "Notice of Appeal") with the U.S. Patent and Trademark Office ("USPTO") on March 24, 2008.

The Appellant respectfully electronically submits this brief on appeal with the statutory fee of $255.00. Payment of the statutory fee occurred at the time of electronic filing. In the event Appellant has inadvertently overlooked the need for an additional payment of a fee which may be required, Appellant conditionally petitions therefor, and authorizes any fee deficiency to be charged or any overpayment to be credited to deposit account 09-0007. When doing so, please reference docket number P00903-US-01 (21934.0001).

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REAL PARTY IN INTEREST

Inventor LENEAU, Harry assigned his invention to Leneau Holdings, LLC, an Indiana limited liability company having a present address of 18753 County Lane 170, Jasper, Missouri 64775. This assignment was recorded with the USPTO on November 7, 2006, at Reel/Frame No. 018508/0326. Leneau Holdings, LLC, shall be referred to herein as the "Appellant."

RELATED APPEALS AND INTERFERENCES

The Appellant and its legal representative are presently unaware of any appeal or interference which will directly affect, be directly affected by, or have a bearing on the Board.

STATUS OF CLAIMS

Claims 1-13 have been rejected under 35 U.S.C. § 102(e) pursuant to the Final Office Action." In response to the Final Office Action, Appellant filed a Response to Office Action (the "Response") on November 26, 2007, amending claim 12 to place it in independent form, cancelling claim 11 accordingly, providing comments in response to the 35 U.S.C. § 102(e) rejection contained within the Office Action, and requesting an Advisory Action. In response to the Response, the Supervisory Examiner mailed the First Advisory Action on January 30, 2008, rejecting the then-pending claims 1-10 and 12-13. In response to the First Advisory Action and a teleconference with the Supervisory Examiner on February 28, 2008, Appellant subsequently filed an Amendment After Final to Place the Application in a Condition for Allowance (the "Amendment After Final") on February 29, 2008, amending claims 1 and 13 and cancelling claims 2 and 12. As the Second Advisory Action was not mailed until March 31, 2008, Appellant filed the Notice of Appeal of March 24, 2008, to meet the statutory filing deadline. On March 31, 2008, and in response to the Amendment After Final, the Examiner mailed the Second Advisory Action, rejecting the then-pending claims 1, 3-10, and 13. Claims 1, 3-10, and 13 are presented for appeal. Claims 2, 11, and 12 have previously been cancelled. A copy of the presented claims is provided in the "Claims Appendix" in section **VI** herein.

STATUS OF AMENDMENTS

After receipt of the Final Office Action, Appellant filed the Response to Office Action amending dependent claim 12 to place it in independent form, cancelling independent claim 11 accordingly. In response to the First Advisory Action and a teleconference with the Supervisory Examiner on February 28, 2008, Appellant subsequently filed the Amendment After Final amending claims 1 to make it "closed-ended," cancelled claim 2 as a result of amending claim 1, cancelled claim 12 to facilitate allowance of the Application, and amended claim 13 to depend from claim 1. As a result of these claim amendments and cancellations, claims 1, 3-10, and 13 are presented for appeal.

SUMMARY OF CLAIMED SUBJECT MATTER

Regarding the appeal brief disclosures required under 37 C.F.R. § 41.37(c)(1)(v), Appellant offers the following concise explanation of the subject matter defined in the independent claims involved in the appeal.

The Application discloses a nutritional supplement and method for relieving joint pain and other discomforts associated with joint disorders in warm-blooded vertebrates by the oral delivery of said nutritional supplement.

With respect to claim 1 (the sole independent method claim currently pending in the Application), a "method for relieving joint pain or other discomforts with joint disorders in a warm-blooded vertebrate" is claimed. As discussed within paragraph 0013 of the Application, "the present method provides relief from joint pain and musculoskeletal discomfort in a warm-blooded vertebrate suffering from an arthritic condition or fibromyalgia." As referenced within the Application, "[a]n arthritic condition includes acute and chronic rheumatoid arthritis and osteoarthritis, as well as inflammatory conditions involving skeletal conditions and musculoskeletal conditions." Application, paragraph 0013.

Claim 1 further comprises language that the method is "consisting of the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier..." Appellant respectfully submits that as provided within paragraph 0014 of the application, the disclosed method comprises "delivering to the vertebrate by oral ingestion a composition comprising an effective amount of hyaluronic acid, or a salt or digest thereof, and a

nutritionally acceptable carrier." Example 1 of the Application provides information regarding a study of sixty-seven patients suffering from arthritis, whereby "[e]ach patient received 1-4 mg of hyaluronic acid by oral ingestion administration 1 to 4 times daily over periods ranging from about 4 to about 2 weeks..." Application, paragraph 0016.

Claim 1 further claims that "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1μg to about 400 μg/kg of body weight." Direct support for this portion of claim 1 may be found in paragraph 0014 of the Application, stating that "[t]he effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1μg/kg to about 400 μg/kg of body weight per dose."

With respect to claim 8 (the sole independent composition claim currently pending in the Application), "[a] nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, the nutritional supplement provided in an orally ingestible dosage form" is claimed. Support for each element of claim 8 is as provided above with respect to claim 1.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the Examiner erred in rejecting claims 1, 3-10, and 13 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,924,273 to Pierce ("Pierce").

2. Whether the Examiner erred in considering the teaching cited by the Examiner as sufficient prior art under 35 U.S.C. § 102(e).

ARGUMENT

I. PIERCE DOES NOT CONSTITUTE PRIOR ART TO THE PRESENT APPLICATION AS THE DISCLOSURE OF THE PROVISIONAL APPLICATION FOR WHICH PIERCE CLAIMS PRIORITY DID NOT SUFFICIENTLY ENABLE THE PIERCE NON-PROVISIONAL PATENT APPLICATION

Appellant respectfully submits that Pierce does not qualify as prior art to the present Application. Specifically, the provisional patent application for which Pierce claims priority ***did not sufficiently enable*** the disclosure of the non-provisional Pierce application, and as such, the effective date of Pierce for purposes of its potential applicability to the present analysis prohibits Pierce from constituting prior art to the present Application.

A. THE PROCEDURAL HISTORY OF THE PIERCE APPLICATIONS

On October 3, 2000, the attorney for inventor Scott Pierce, John F. Dolan, filed U.S. Provisional Application No. 60/237,838, entitled "CHONDROPROTECTIVE/RESTORATIVE COMPOSITIONS AND METHODS THEREOF" (the "'838 Application"). On October 2, 2001, another attorney for Scott Pierce, Isaac A. Angres, filed U.S. Nonprovisional Patent Application No. 09/967,977, entitled "CHONDROPROTECTIVE/RESTORATIVE COMPOSITIONS AND METHODS THEREOF" (the "'977 Application"), claiming priority back to U.S. Provisional Application No. 60/237,838. The '977 Application eventually issued as U.S. Patent No. 6,924,273 on August 2, 2005.

B. THE PROCEDURAL HISTORY OF THE LENEAU APPLICATIONS

On May 18, 2001, the attorney for inventor Harry Leneau, Jill Powlick of Barnes & Thornburg, filed U.S. Nonprovisional Application No. 09/860,425, entitled "INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT FUNCTION AND HEALTH" (the "'425 Application"). The '425 Application eventually issued as U.S. Patent No. 6,607,745 on August 19, 2003. Prior to the issuance of the '745 Patent, the same attorney for inventor Harry Leneau filed a continuation-in-part application, namely U.S. Nonprovisional Application No. 10/629,880, entitled "INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT FUNCTION AND HEALTH" (the "'880 Application"). The '880 Application claimed priority back to the '425 Application.

C. THE "INVENTION" OF THE '838 APPLICATION IS CLEARLY A COMPOSITION CONTAINING GLUCOSAMINE SULFATE, CHONDROITIN SULFATE, AND HYALURONIC ACID, AND NOT HYALURONIC ACID ALONE

Appellant respectfully submits that the "invention" disclosed by the Pierce '838 Application is clearly a composition containing glucosamine sulfate, chondroitin sulfate, and hyaluronic acid, and not a composition containing hyaluronic acid alone. The '838 Application, filed on October 3, 2000, disclosed a composition called "Chondrogen EQ" which was allegedly "the most unique chondroprotective / restorative agent available." '838 Application, page 1. The '838 Application, as shown by numerous references therein, makes it clear what the "invention" was within the '838 Application:

- "***The present invention***, which goes by the name Chondrogen EQ, was initially formulated ..." (emphasis added). '838 Application, page 1.

- "This highly palatable formulation is the first ***to combine high levels of Glucosamine sulfate (GS) with Chondroitin sulfate (CS) and Hyaluronic Acid (HA)*** in an easy to absorb, low molecular weight formula." (emphasis added) '838 Application, page 1.

- "***The present invention, with it's unique combination of GS, CS, and HA*** ..." (emphasis added). '838 Application, page 1.

- "As previously explained, ***the present invention comprises a highly palatable formulation, which is the first to combine high levels of Glucosamine sulfate (GS) with Chondroitin sulfate (CS) and Hyaluronic Acid (HA)*** ..." (emphasis added). '838 Application, page 3.

- "There is a beneficial effect when ***Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid*** are administered orally. Generally, the oral administration of embodiments ***of the present composition has a quicker clinical response than is produced when each component of the composition is given individually. A significant difference*** is an acute or a rapid relief in joint pain inflammation and swelling achieved by oral administration of the composition." (emphasis added) '838 Application, pages 4-5.

- "Another benefit is that ***embodiments of the present invention, with it's high dose of Glucosamine sulfate, Hyaluronic acid, and Chondroitin sulfate***, appears to have a synergistic effect which hastens the clinical response." (emphasis added) '838 Application, page 5.

- "***One embodiment of the present invention is a unique formulation that combines Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid into a paste formulation*** ..." (emphasis added). '838 Application, page 5.

- "Early clinical trials have shown that ***when the three products are combined,*** they have a synergistic effect." (emphasis added) '838 Application, pages 5-6.

- "***Embodiments of the present invention possess the following advantages***: ... 2) ***Only combination of GS, CS, HA in a paste formulation*** ..." (emphasis added). '838 Application, page 6.

- "Because of their chemical similarities and the clinical reports of improvement of synovitis, ***HA has a synergistic effect with GS and CS when given orally***." ..." (emphasis added). '838 Application, page 9.

As is shown by these statements within the '838 Application, it is clear that the "invention" of the '838 Application is a combination of Glucosamine sulfate (GS), Chondroitin sulfate (CS) and Hyaluronic Acid (HA). Additional support for this conclusion can be found ***in the only two exemplary formulations provided in the '838 Application***:

- Page 7: Embodiment comprising 46.03% Glucosamine sulfate, 4.60% Chondroitin sulfate, and 0.18% Sodium hyaluronate. In this embodiment, of the 50.81% (46.03% + 4.60% + 0.18%) combined active ingredients, only 0.35% (0.18%/50.81%) of the total active ingredients is sodium hyaluronate (the sodium salt of hyaluronic acid).

- Page 11 (unnumbered – page appearing after numbered page 10): Chondrogen EQ formulation comprising 36% Glucosamine sulfate, 4% Chondroitin sulfate, and 0.144% Sodium hyaluronate. In this embodiment, of the 40.144% (36% + 4% + 0.144%) combined active ingredients, only 0.36% (0.144%/40.144%) of the total active ingredients is sodium hyaluronate (the sodium salt of hyaluronic acid).

As is clearly shown, these two formulations only contain a very minor fraction of sodium hyaluronate (0.18% and 0.144%, respectively) as compared to the remaining ingredients. When viewing the three named active ingredients of the "invention" of the '838 Application (namely glucosamine sulfate, chondroitin sulfate and hyaluronic acid), sodium hyaluronate only comprises 0.35% and 0.36%, respectively, of those two formulations. In the first formulation, for example, the weight ratio to the largest active ingredient (glucosamine sulfate) to sodium hyaluronate is over 255 to 1. In the second formulation, the weight ratio of glucosamine sulfate to sodium hyaluronate is also very high (250 to 1). Appellant respectfully submits that it is quite clear that the "invention" of Pierce was not solely a hyaluronic acid composition.

D. THE '838 APPLICATION INTRODUCED, BUT DID NOT ENABLE, AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT ALSO CONTAINING GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE

Appellant respectfully submits that the '838 Application introduced, but did not enable, an orally administrable composition containing an effective amount of hyaluronic acid without also containing glucosamine sulfate and chondroitin sulfate. Appellant acknowledges that the '838 Application does discuss the concept of oral administration of hyaluronic acid ("HA"), but Appellant respectfully submits that the introduction of this concept within the '838 Application included no evidence whatsoever to support the conclusions made therein. For example, page 5 of the '838 Application states the following:

> Another benefit received is that of oral preparation and administration of HA given, for example, in the equine in any formulation. The administration of the HA composition orally and having a clinical effect eliminates more evasive procedures.

In addition, page 9 of the '838 Application states the following:

> Clinically, responses are seen in 7 to 10 days vs three to four weeks or not at all when GS and CS are given without HA. Therefore, we have seen a dramatic decrease in synovitis when HA is combined with GS and CS. ***This leads us to conclude that HA is absorbed orally and effective*** either ***alone*** or in combination with GS and CS. Therefore, an additional embodiment of the invention comprises a composition including HA and any acceptable carrier, such as the paste formulation disclosed herein and any other liquid, powder, gel or similar type carrier. (emphasis added).

Appellant respectfully submits that although the '838 Application states that "an additional embodiment of the invention comprises a composition including HA and any acceptable carrier," ***this statement contains no support from any other portion of the '838***

Application and actually contradicts other statements in the application. This particular statement follows the prior two sentences in the '838 Application which state (in summary) that clinical responses are seen when GS and CS are provided ***without HA***, and that a dramatic decrease in synovitis is seen ***when HA is combined with GS and CS***. As the '838 Application clearly discloses and intends to focus on an orally administrable composition containing GS, CS, and HA, a conclusion that the oral administration of HA alone without any evidence in support and that contradicts other statements within the same application is clearly not enabled.

E. THE ONLY SUPPORT WITHIN THE PIERCE APPLICATIONS FOR AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE APPEARED WITHIN THE '977 APPLICATION AND NOT THE '838 APPLICATION

Appellant respectfully submits that the only support within the Pierce applications for an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate appeared within the nonprovisional '977 Application and not the provisional '838 Application. As discussed in Section I(C) above, the '838 Application introduced, but provided no support for, an orally administrable composition containing an effective amount of hyaluronic acid without also containing glucosamine sulfate and chondroitin sulfate.

Appellant respectfully submits that support for such a product was first introduced on page 10 of the '977 Application. Starting on page 10, the '977 Application discusses the treatment of ten horses with an oral gel and provides data regarding the same on Tables 1 and 2

appearing on pages 12-13. By way of example, the "TREATED HORSES" section of Table 2 shows that horses 101, 105, 106, and 109 "Improved" during treatment using the hyaluronic acid gel.

Appellant respectfully submits that this data, first appearing in the '977 Application, is the first time the concept of an "effective" orally administrable composition containing hyaluronic acid and not containing glucosamine sulfate and chondroitin sulfate was enabled in either of the Pierce applications.

F. BECAUSE THE '838 APPLICATION DID NOT ENABLE AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE, PIERCE IS NOT PRIOR ART WITH RESPECT TO THE PRESENT APPLICATION

Appellant respectfully submits that because the '838 Application did not enable an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate, Pierce is not prior art with respect to the present Application.

Appellant respectfully submits that the parent application to the present Application, namely the '425 Application, was filed on May 18, 2001. Pierce's provisional application (the '838 Application) was filed on October 3, 2000, approximately 7 ½ months prior to the filing of the '425 Application. Pierce then converted the '838 Application to the '977 Application on October 2, 2001, approximately 4 ½ months after Leneau filed the parent application (the '425

Application) to the present Application (the '880 Application) claiming priority to the '425 Application.

Appellant respectfully submits that as pertaining to any orally administrable composition which may be disclosed within either of the Pierce applications that contains hyaluronic acid but not glucosamine sulfate or chondroitin sulfate, the '977 Application, and not the '838 Application, provides data enabling such a composition. Accordingly, and because the '977 Application was filed ***after*** the parent application (the '425 Application) for which the present Application (the '425 Application) claims priority, Pierce ***cannot*** be considered prior art with respect to such a composition. Accordingly, Appellant respectfully submits that the Pierce patent is not prior art to the present Application, and as such, Appellant respectfully requests that the Examiner withdraw the rejection of the pending claims under 35 U.S.C. § 102(e) and allow claims 1, 3-10, and 13 to proceed to allowance.

II. THE CLAIMS OF THE PRESENT APPLICATION DO NOT CLAIM THE SAME SUBJECT MATTER AS PIERCE

Appellant respectfully submits that because the pending Application is not claiming the same invention as Pierce, and because there is a patentable distinction between the claims of the Application and the claims of Pierce, the limitations of MPEP 715.05 do not apply to the present Application.

Appellant previously submitted a Declaration of Prior Inventorship in the United States (37 C.F.R. § 1.131) (the "Declaration") along with the Response to Office Action dated May 4, 2006. A copy of the Declaration is enclosed for reference. The Declaration provided sufficient

proof to demonstrate that the subject matter of the Application "was conceived and reduced to practice at least by the date November 5, 1999, which is a date earlier than the effective date of U.S. Patent No. 6,924,273, namely October 3, 2000." As such, Appellant respectfully submits that the Declaration is effective to overcome the 35 U.S.C. § 102(e) rejection based upon Pierce. Specifically, because the claims, in their present form, do not claim the same invention as Pierce, the previously submitted Declaration is effective to overcome the maintained 35 U.S.C. § 102(e) rejection.

The claims of the Application, in their present form, include claims for a method for relieving joint pain or other discomforts associated with joint disorders and claims for a nutritional supplement. Pierce includes nine (9) method claims (claims 20-28) and nineteen (19) composition claims (claims 1-19). Appellant respectfully submits that as is demonstrated below, the claims of the present Application ***do not claim the same invention*** as claimed in Pierce.

A. THE METHOD CLAIMS

Appellant respectfully submits that the method claims of the present Application, in their present form, ***do not claim the same invention*** as claimed in the method claims of Pierce.

Claims 20-28 of Pierce are the only method claims included within Pierce. Claim 20, the only independent method claim of Pierce, includes the following general elements:

a. "A method of treating osteoarthritis...[and other disorders]..., said method comprising..."
b. "...orally administering..."
c. "...to [a] mammal..."
d. "...a therapeutically effective amount..."
e. "...of the composition of claim 1."

Regarding method element (e) above, the composition of claim 1 of Pierce includes the following elements:

w. "An orally administrable Chondroprotective/Restorative composition..."
x. "...gel or paste form..."
y. "...an effective amount of hyaluronic acid or its pharmaceutically acceptable salts..."
z. "...a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or a paste selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses."

Accordingly, Appellant respectfully submits that claim 20 of Pierce, considering that method element (e) above references the composition described in composition elements (w) through (z), effectively includes method elements (a) through (d) and composition elements (w) through (z).

The present Application contains seven (7) currently-pending method claims, namely claims 1, 2-7, and 13. Claim 1 is the sole independent method claim of the Application, and by definition, it is the claim within the Application with the broadest scope (the fewest elements). Appellant's claim 1 contains the following elements:

i. "A method for relieving joint pain or other discomforts associated with joint disorders..."
ii. "...in a warm blooded vertebrate..."
iii. "...consisting of the step of delivering to said vertebrate by oral ingestion..."
iv. "...a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof..."
v. "...wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight."

Appellant respectfully submits that claim 20 of Pierce, effectively including composition elements (w) through (z) of claim 1 of Pierce, ***does not claim the same invention*** as claimed in Appellant's claim 1. Appellant respectfully submits the following list of differences between the two claims:

1. Composition element (x) of Pierce requires the composition to be in "gel or paste form." This element does not appear in Appellant's claim 1, which does not require the nutritional supplement referenced therein to be in "gel or paste form."

2. Composition element (z) of Pierce requires a "pharmaceutically acceptable gelling or pasting agent capable of forming a gel or a paste selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses." This element does not appear in Appellant's claim 1, which does not require the nutritional supplement referenced therein to include any type of "gelling or pasting agent."

3. Method element (v) of Appellant's claim 1 requires that "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight." Claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not provide for any specific range of hyaluronic acid or its pharmaceutically acceptable salts.

Appellant respectfully submits that as provided above, Appellant's method claims differ from the method claims of Pierce, and accordingly, Appellant's method claims do not claim the same invention as the method claims of Pierce.

B. THE COMPOSITION CLAIMS

Appellant respectfully submits that the composition claims of the present Application, as amended, ***do not claim the same invention*** as claimed in the composition claims of Pierce.

Claims 1-19 of Pierce are the only composition claims included within Pierce. Appellant respectfully submits that no composition claim of Pierce claims the same invention as claimed in any of Appellant's pending composition claims.

Appellant respectfully submits that none of the composition claims of Pierce (claims 1-19) need to be considered as relevant to the present inquiry ***as each claim requires effective amounts of additional ingredients not claimed in Appellant's composition claims***. Specifically, the following claims of Pierce require the inclusion of one or more additional supplements/ingredients not required in Appellant's composition claims:

Claim 1: requires, at a minimum, "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste", with the gelling or pasting agent "selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses."

Claim 2: requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 3: requires, at a minimum, "an effective amount of Glucosamine sulfate"

Claim 4: depends upon claim 3, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 5: requires, at a minimum, "an effective amount of Chondroitin sulfate"

Claim 6: depends upon claim 5, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 7: requires, at a minimum, "an effective amount of Glucosamine sulfate" and an effective amount of Chondroitin sulfate"

Claim 8: depends upon claim 7, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 9: requires, at a minimum, "an effective amount of a therapeutic drug" aside from hyaluronic acid and "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste"

Claim 10: depends upon claim 9, and requires that the therapeutic drug be selected from a group consisting over 200 compounds provided therein

Claim 11: claims a composition "in paste form" and requires, at a minimum, "a sufficient amount of molasses to make a paste."

Claim 12: depends upon claim 11, and requires, at a minimum, glucosamine sulfate

Claim 13: depends upon claim 12, and further requires "nutritionally effective amounts of vitamins and minerals"

Claim 14: depends upon claim 11, and requires, at a minimum, chondroitin sulfate

Claim 15: requires, at a minimum, "a sufficient amount of carboxymethylcellulose or its sodium salt to make a gel"

Claim 16: depends upon claim 15, and further requires glucosamine sulfate

Claim 17: depends upon claim 15, and further requires chondroitin sulfate

Claim 18: depends upon claim 15, and further requires "nutritionally effective amounts of vitamins and minerals"

Claim 19: depends upon claim 18, and further requires chondroitin sulfate

Appellant's claims 8-10 are the only composition claims included within the present Application. Appellant's claim 8, the only independent composition claim pending in the Application, includes the following general elements:

A. "A nutritional supplement consisting essentially of..."
B. "..an effective amount of hyaluronic acid, or a salt or digest thereof..."

C. "...and a food acceptable carrier..."
D. "...the nutritional supplement provided in an orally ingestible dosage form."

Appellant's claim 9, depending upon claim 8, includes the following element:

E. "...wherein the effective amount of hyaluronic acid is 1 to 6 mg."

Appellant's claim 10, which also depends upon claim 8, includes the following element:

F. "...wherein the orally ingestible dosage form is a capsule or gel seal."

Appellant respectfully submits that composition claims 8-10 of the Application neither contain nor require the supplements/ingredients identified above with respect to composition claims 1-19 of Pierce. Furthermore, as shown immediately above and as similarly referenced with respect to Appellant's method claim 1, Appellant's composition claim 8 includes a nutritional supplement "and a food acceptable carrier." Appellant respectfully submits that composition claims 1-19 of Pierce do not include the element or limitation of a composition "and a food acceptable carrier" as claimed in Appellant's composition claim 8.

Accordingly, Appellant respectfully submits that as provided above, Appellant's composition claims differ from the composition claims of Pierce, and accordingly, Appellant's composition claims do not claim the same invention as the composition claims of Pierce.

C. THERE IS A PATENTABLE DISTINCTION BETWEEN THE CLAIMS OF THE APPLICATION AND THE CLAIMS OF PIERCE

Appellant respectfully submits that because the currently-pending claims of the Application are patently distinct from the claims of Pierce, the limitations of MPEP 715.05 do not apply. Specifically, because the claims of the Application are patently distinct from the

claims of Pierce, the previously submitted Declaration is effective to overcome the rejection under 35 U.S.C. § 102(e).

Appellant respectfully submits that in a similar fashion as described above with respect to the method and composition claims of the present Application and Pierce not claiming the same invention, those claims are also patently distinct from one another.

For example, the only independent method claim of Pierce (claim 20) claims a method of treating osteoarthritis and other disorders using the composition of claim 1 of Pierce. This method claim is patently distinct from the broadest method claim of the present Application (claim 1) as (1) Pierce requires the composition to be in "gel or paste form" which is not required by Appellant's claim 1, (2) Pierce requires a "pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste," with the gelling or pasting agent "selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses" which is not required by Appellant's claim 1, and (3) Appellant's claim 1 requires "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight," while claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not provide for any specific range of hyaluronic acid or its pharmaceutically acceptable salts. As is clearly shown by these exemplary comparisons, the method claims of the present Application are patentably distinct from the method claims of Pierce.

A similar conclusion can be made with respect to the composition claims. As referenced above, each of claims 1-19 of Pierce requires at least one additional supplement/ingredient than is claimed in Appellant's composition claims 8-10. By way of example, (1) claim 1 of Pierce requires "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste," (2) claims 2, 4, 6, 8, 13, and 18 of Pierce require "vitamins and minerals," (3) claims 3, 7, 12, and 16 of Pierce require glucosamine sulfate, and (4) claims 5, 7, 14, 17 and 19 of Pierce require chondroitin sulfate, each of which is not claimed or required by Appellant's composition claims 8-10. As is also clearly shown by these exemplary comparisons, the composition claims of the present Application are patentably distinct from the composition claims of Pierce.

III. PLUS SEARCH

Appellant respectfully submits that in addition to the foregoing, *prima facie* evidence of Appellant's conclusion can be found when reviewing the prosecution history of Pierce. During the prosecution of Pierce, Examiner Devesh Khare performed a Patent Linguistics Utility System ("PLUS") search on October 22, 2004. The date of this search is indicated on the Search Notes document for the Pierce application, a copy of which is enclosed for reference. Applicant respectfully submits that as noted within the enclosed PLUS search results, PLUS "is a USPTO automated search system of U.S. Patents from 1971 to the present," and does not search pending patent applications.

The PLUS search performed by Examiner Khare identified fifty (50) patent references, some of which are duplicate results. One of the patents identified by the PLUS search was U.S.

Patent No. 6,607,745 to Leneau et al. (the "'745 Patent") (indicated by the arrow written in by counsel for Appellant), which is significant as the '745 Patent is the parent patent to the present Application. The present Application is a continuation-in-part of the application resulting in the '745 Patent.

Appellant respectfully submits that although the '745 Patent, and not the present Application, was identified in the PLUS search, the present application claims priority to the '745 Patent, and contains substantially the same disclosure as the application leading to the '745 Patent. ***As the entire specification of the '745 Patent is present within the present Application, Appellant respectfully submits that the PLUS search, if expanded to include pending patent applications, would have also identified the pending Application.***

Appellant respectfully submits that although the '745 Patent was identified by Examiner Khare, the next formal action taken by Examiner Khare, aside from the submission of interview summary documents, was the submission of a Notice of Allowability and a Notice of Allowance and Fees Due for the Pierce patent application. The '745 Patent was never referenced by Examiner Khare in a Notice of References Cited accompanying any office action issued during the prosecution of Pierce, and accordingly, Appellant respectfully submits that the identification of the '745 Patent in the PLUS search and the lack of citation of that reference by Examiner Khare in any office action of Notice of References Cited is *prima facie* evidence that the '745 Patent was patently distinct from Pierce.

In an office action dated May 4, 2006, the Examiner of the present Application presented a rejection of claims 1-13 on the ground of nonstatutory obviousness-type double patenting as

being unpatentable over claims 1-7 of U.S. Patent No. 6,607,745. In that rejection, the Examiner noted that the conflicting claims were "not identical," but that they were "not patentably distinct from each other" for the reasons provided therein. In response, Appellant submitted a terminal disclaimer along with the response to the May 4, 2006 office action to obviate the rejection of claims 1-13.

Appellant respectfully submits that as the claims of the present Application were deemed to be "not patentably distinct" from claims 1-7 of the '745 Patent, and because Appellant filed a terminal disclaimer that was accepted by the Examiner, the claims of the present Application should be viewed in a similar fashion as were the claims of the '745 Patent as reviewed by Examiner Khare during the prosecution of Pierce. Specifically, Appellant respectfully submits that if the claims of the '745 Patent were not deemed to be material to the prosecution of Pierce, and because the Examiner of the present Application has stated that specific claims of the '745 Patent are "not patentably distinct" from the claims of the present Application, the claims of the present Application are patentably distinct from the claims of Pierce.

Accordingly, Appellant respectfully submits that because the pending Application is not claiming the same invention as Pierce, and because there is a patentable distinction between the claims of the Application and the claims of Pierce, the limitations of MPEP 715.05 do not apply to the previously submitted Declaration, and the Declaration is effective to overcome the 35 U.S.C. § 102(e) rejection based upon Pierce. Accordingly, Appellant respectfully requests that the Examiner withdraw the rejection of the pending claims under 35 U.S.C. § 102(e) and allow claims 1, 3-10, and 13 to proceed to allowance.

IV. CONCLUSION

In summary, and as described above, the Examiner erred in rejecting the pending claims of the Application under 35 U.S.C. § 102(e) as being anticipated by Pierce. In addition, Pierce does not suffice as 35 U.S.C. § 102(e) prior art as the disclosure of the provisional application for which Pierce claims priority did not sufficiently enable Pierce. Therefore, Appellant respectfully requests that the rejection of the pending claims under 35 U.S.C. § 102(e) be withdrawn and that claims 1, 3-10, and 13 be allowed as patentable subject matter.

Respectfully submitted,

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MCR/
Enclosures: Transmittal Form
Copy of U.S. Patent Application Serial No. 09/860,425 to Leneau
Copy of U.S. Patent No. 6,607,745 to Leneau
Copy of U.S. Patent Application Serial No. 10/629,880 to Leneau
Copy of U.S. Patent Application Serial No. 60/237,838 to Pierce
Copy of U.S. Patent Application Serial No. 09/967,977 to Pierce
Copy of U.S. Patent No. 6,924,273 to Pierce
Copy of Office Action dated May 4, 2006
Copy of Response to Office Action dated November 3, 2006, with attachments
Copy of Office Action dated September 24, 2007
Copy of Response to Office Action dated November 26, 2007, with attachments
Copy of First Advisory Action dated January 30, 2008

Copy of Amendment After Final to Place the Application in a Condition for Allowance dated February 29, 2008

Copy of Second Advisory Action dated March 31, 2008

V. CLAIMS APPENDIX

1. (Previously presented) A method for relieving joint pain or other discomforts associated with joint disorders in a warm-blooded vertebrate consisting of the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight.

2. (Cancelled)

3. (Original) The method of claim 1 wherein the nutritional supplement is provided in capsule form.

4. (Original) The method of claim 1 wherein the warm-blooded vertebrate is a human, or an equine, canine, or feline species.

5. (Original) The method of claim 1 wherein the joint pain is the result of an arthritic condition.

6. (Original) The method of claim 5 wherein the arthritic condition is selected from the group consisting of osteoarthritis and rheumatoid arthritis.

7. (Original) The method of claim 1 wherein the joint pain is the result of an inflammatory condition involving skeletal or musculoskeletal structures.

8. (Original) A nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, the nutritional supplement provided in an orally ingestible dosage form.

9. (Original) The nutritional supplement of claim 8, wherein the effective amount of hyaluronic acid is 1 to 6 mg.

10. (Original) The nutritional supplement of claim 8 wherein the orally ingestible dosage form is a capsule or gel seal.

11. (Cancelled)

12. (Cancelled)

13. (Previously presented) The method of claim 1 wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is provided in liquid form.

V. EVIDENCE APPENDIX

U.S. Patent Application Serial No. 09/860,425 to Leneau (copy attached).

U.S. Patent No. 6,607,745 to Leneau (copy attached).

U.S. Patent Application Serial No. 10/629,880 to Leneau (copy attached).

U.S. Patent Application Serial No. 60/237,838 to Pierce (copy attached).

U.S. Patent Application Serial No. 09/967,977 to Pierce (copy attached).

U.S. Patent No. 6,924,273 to Pierce (copy attached).

Copy of Office Action dated May 4, 2006 (copy attached).

Copy of Response to Office Action dated November 3, 2006, with attachments (copy attached).

Copy of Office Action dated September 24, 2007 (copy attached).

Copy of Response to Office Action dated November 26, 2007, with attachments (copy attached).

Copy of First Advisory Action dated January 30, 2008 (copy attached).

Copy of Amendment After Final to Place the Application in a Condition for Allowance dated February 29, 2008 (copy attached).

Copy of Second Advisory Action dated March 31, 2008 (copy attached).

VII. RELATED PROCEEDINGS APPENDIX

None.